Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DENIS CORPET,
SYLVIANE TACHE and GERALDINE PARNAUD

Appeal No. 2004-1790
Application No. 09/836,971

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 6, 8-12 and 14-19. Claim 6 and 12 are representative of the subject matter on appeal, and read as follows:

> 6. A method of treating colon[1] or rectum cancer comprising administering to a mammal a therapeutically effective amount of a non-fermented osmotic polyol laxative.

[1] We note that the appendix to the Appeal Brief states "color" cancer, but our review of the file indicates that the use of "color" for "colon" is a typographical error.

> 12. A method of preventing colon or rectum cancer comprising administering to a mammal a therapeutically effective amount of a non-fermented osmotic polyol laxative.

The examiner relies upon the following reference:

Crowson et al. (Crowson), "The use and efficacy of cytocidal agents in colorectal Cancer," Surg. Res. Comm., Vol. 2, pp. 97-101 (1987).

Claim 12 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure. In addition, claims 6, 8, 12 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Crowson, and claims 9-11 and 15-19 stand rejected under 35 U.S.C. § 103(a) as being obvious over Crowson. After careful review of the record and consideration of the issues before us, we reverse.

DISCUSSION

1. Rejection under 35 U.S.C. § 112, first paragraph

Claim 12 stands rejected under 35 U.S.C. § 112, first paragraph. The statement of the rejection states that the grounds of the rejection are that "the specification, while being enabling for treating colon or rectum cancer with PEG or pluronic does not reasonably provide enablement for treating colon or rectum cancer with all non-fermenting osmotic laxatives." Examiner's Answer, page 4. At the end of the rejection, however, see id. at 6, and again in the response to arguments, see id. at 8, the examiner states that the rejection is directed to the use of the claimed method in preventing cancer. We thus limit our analysis of the rejection to the use of the claimed method in preventing cancer.

The rejection specifically addresses three of the Wands factors; 1) breadth of the claims; 2) state of the art; and 3) guidance of the specification, and examples. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). With respect to breadth of the claims, the rejection asserts that the recitation of preventing "extend[s] the treatment to those patients in which rectal and colon cancers may occur at any point of time in [the] future." See Examiner's Answer, page 5. With respect to the state of the art, the examiner apparently recognizes that "[t]he state of the art recognizes that increased intake of dietary fibers contribute to the increased bowel movements and thus result in lowering the risk of colon cancers," but asserts that "the art does not teach or recognize a complete prevention of the above claimed cancers." See id. Finally, with respect to guidance of the specification and examples, the examiner focuses on the lack of teaching of an understanding of when the cancer may occur. The rejection thus contends that the specification provides no examples of long term trials, and fails to "teach at what time point or the duration of time that the claimed cancers would take to develop." Id. Moreover, according to the rejection, the specification "does not provide any guidance as to how long one has to administer the instant laxatives so as to prevent the occurrence of colon or rectum cancer." Id.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first

paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided "acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

The rejection appears to be requiring precise predictability as to the time when the colon or rectal cancer will appear, and also appears to require 100% prevention. That is not, however, a requirement under 35 U.S.C. § 112, first paragraph. "Usefulness in patent law, and in particular the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." In re Brana, 51 F.3d, 1560, 1568 34 USPQ2d 1436, 1442-43 (Fed. Cir. 1995) (citations omitted).

Moreover, as noted by appellants, page 11 of the specification includes a study of a multiplicity of rats, and results of "extremely substantial inhibition" are achieved. See Appeal Brief, pages 6-7. The examiner in response to arguments, however, rejects that showing on the basis that "[a]pplicants . . .

agree that the rat model employed in the specification is different from the human model" that "proves [the] examiner's position that prevention is related to factors such as the length of time the tumor takes to manifest, type of animal being studied, etc." Examiner's Answer, page 8. But as we noted above, absolute predictability is not required. In addition, appellants' admission is merely that "a rat model is a far shorter model which is fully described in the . . . Specification such that one of ordinary skill in the art could readily practice the subject matter in Claim 12 without undue experimentation." Appeal Brief, page 8.

Thus, we find that the examiner has not met the burden of demonstrating that the claim 12, drawn to "[a] method of preventing colon or rectum cancer," is not enabled, and the rejection is reversed.

2. Rejection under 35 U.S.C. § 102(b)

Claims 6, 8, 12 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Crowson. According to the rejection:

> Crowson [ ] teaches several cytocidal agents and bowel preparation agents that are capable of killing HT 29 colorectal cancer cell line and thus protection against colorectal cancer. The bowel preparation agents include polyethylene glycol (PEG). Although Crowson observes less activity or efficacy with PEG as compared to cetrimide, the instant claims do not recite the amount of activity. Further, PEG exhibits as high as 30 and 36 percent cytocidal activity, which is very significant (table IV). Accordingly, the teachings meet the claim requirement. Although Crowson fails to mention non-fermenting osmotic laxative, the property is inherent to PEG of Crowson.

Examiner's Answer, page 6.

Appellants argue that "Crowson has a critical and fatal flaw. Crowson exposes HT 29 colorectal cancer cells, in vitro, to various agents. There is not one word concerning administration of the agents to a mammal as explicitly claimed by the Appellants." Appeal Brief, pages 9-10 (emphasis in original).

We agree. In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). The examiner asserts that "Crowson discloses that HT29 colorectal cells are of known malignancy and PEG inhibits the growth of HT29 cancer cell lines," arguing that "it is implicit that PEG is effective in treating or inhibiting colon or rectal cancer." That is not, however, explicit or inherent teaching of administering the PEG to a mammal, thus Crowson fails to teach every limitation of the claimed invention, and the rejection is reversed.

3. Rejection under 35 U.S.C. § 103(a)

Claims 9-11 and 15-19 stand rejected under 35 U.S.C. § 103(a) as being obvious over Crowson. The rejection is set forth below.

> Crowson [ ] (described above) teaches the use and efficacy of several cytocidal and bowel preparation agents such as PEG, cetrimide, povidone iodine, etc. Crowson shows that the compounds are capable of killing colorectal cell lines with different efficacies and concludes that only cetrimide is capable of completely killing the cells. However, the instant claims do not mention the amount of therapeutic activity desired. Besides, PEG still exhibits about 30 to 40% activity, which is considered to be significant. Further, the results in table Iv [sic] shows [sic] that the activity is varies [sic] with the compounds as well as incubation time. Accordingly depending on the amount of activity desired, a skilled artisan would be able to use PEG of Crowson, for different time intervals with an expectation to achieve the desired

> therapeutic activity. . . . The teachings of Crawson [ ] [sic] are also directed to preventing the recurrence of colorectal cancer using cytocidal and bowel preparing agents. Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to use PEG of Crawson [sic] for treating as well as preventing colon or colorectal cancer because PEG is shown to exhibit significant activity (30% and 6%) in killing HT29 colorectal cells.

Examiner's Answer, page 7.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citations omitted). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

Appellants argue that Crowson teaches away from the claimed invention by teaching that water performed better in the in vitro experiments than did the PEG, thus providing no motivation to administer PEG to a mammal. We agree. As demonstrated by Table IV, PEG did not even perform as well as water, and Crowson teaches that cetrimide would be the agent of choice. See Crowson, Table IV and page 100. Thus, the reference provides no motivation to administer PEG to mammal for the treatment or prevention of colon or rectal cancer, and the rejection is reversed.

CONCLUSION

For the reasons set forth above, the rejection of claim 12 stand under 35 U.S.C. § 112, first paragraph, the rejection of claims 6, 8, 12 and 14 under 35

U.S.C. § 102(b) as being anticipated by Crowson, and the rejection of claims 9-11 and 15-19 under 35 U.S.C. § 103(a) as being obvious over Crowson, are reversed.

REVERSED

Toni R. Scheiner Administrative Patent Judge	)
Donald E. Adams Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

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